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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,674	10/02/2003	Nader Najafi	IB - 9	8824

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EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
05/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/677,674	NAJAFI ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *26-57,60,61 and 64-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,58,59,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/6/04,12/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention I in the reply filed on 2/23/09 is acknowledged. Claims 26-57, 60, 64, and 66-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

The election of species requirement between species A and B is withdrawn in light of applicants' admission that the species are obvious variants (see p. 4 of the response filed 2/23/09).

Information Disclosure Statement

The information disclosure statement filed 12/15/08 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In particular, no copy of the Park, Puers, or Harpster references is found in the file. The citations of the reference have been crossed out, and the information referred to therein has not been considered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the six cavity walls and the substrates defining them, as claimed in claim 15, the module having multiple

sensors as claimed in claims 17 and18, and the recess as claimed in claim 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 15-18, 23, 62, and 63 are objected to because of the following informalities:

On the last line of claim 15, “electronics should be replaced with "circuitry".

On line 1 of each of claims 16-18 “the sensors” should be replaced with “the at least one miniature sensor or actuator” since there is no antecedent basis in the claim for “the sensors".

On line 1 of claim 23, “the flexible substrate" should be replaced with "the secondary substrate".

On line 1 of claim 62, "sensor" should be replaced with "said at least one miniature sensor".

On line 1 of claim 63, "sensor" should be replaced with "said at least one miniature sensor or actuator comprises a sensor that".

Appropriate correction is required.

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 recite "The sensor module of claim 15, wherein one or more sensors and/or actuators are present." but claim 15 already recites "at least one miniature sensor or actuator".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9, 15-25, 58, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the first and second substrates" on line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that “second substrates" may refer to the “secondary substrate recited in claim 6. If this is the case, “claim 1” on line 1 of the claim should be replaced with “claim 6" and "and second substrates" should be replaced with "substrate and secondary substrate".

Claim 9 recites the limitation "the connection of said substrate to said coil" on line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because neither claim 1 nor claim 9 recites that the coil and substrate are connected.

Claim 15 recites “a bottom substrate defining a cavity of five of six possible walls”. It is wholly unclear what is meant by this limitation. The applicants should clarify.

Claim 22 recites, “a recess in the bottom substrate”. It is unclear whether this recess is separate from the "bottom substrate cavity" recited in claim 15 (wherein claim 22 depends from claim 15). Claim 23 further recites “the bottom substrate recess”, which limitation is similarly unclear. The applicants should clarify.

Claim 23 recites, “the flexible substrate aligns with the bottom substrate recess with a matched wedge shape". It is unclear whether the substrate or the recess or both has a "matched wedge shape". The applicants should clarify.

Claims 58 and 59 are directed to an apparatus ("sensor module of claim 1") but recite method steps: "said module is used for applications". It is unclear whether an

apparatus or a method is being claimed. The applicants should clarify. Furthermore, it is unclear whether the claims are claiming that the sensor module is being used for the listed diseases or whether the sensor module is being used to detect such diseases. The applicants should further clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 12, 15, 16, 19, 20, 58, 59, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,833,603 to Kovacs et al. in view of US Patent No. 6,409,674 to Brockway et al. Regarding claim 1, Kovacs teaches a miniature self contained sensor module for medical applications comprising at least one substrate 40 (see entire document, especially figs. 2, 3; col. 8, lines 16-28 of Kovacs), at least one miniature sensor 32, disposed in part on the substrate (see entire document, especially figs. 1, 3-11; col. 6, lines 44-51; col. 8, line 47-col. 16, line 65 of Kovacs), and an electrical circuit 36 disposed on the substrate, wherein the circuit receives operating power from a magnetic field with an inductive device, conditions a signal, and transmits a conditioned sensor signal to an external signal detection system via magnetic

telemetry (see entire document, especially figs. 2, 3; col. 6, line 28-col. 7, line 16 of Kovacs). Kovacs is silent as to the details inductive circuit or device.

However, Brockway teaches a miniature self contained sensor module for medical applications comprising an electrical circuit that receives operating power from a magnetic field with an inductor coil (see entire document, especially col. 10, lines 1-25 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the inductor coil of Brockway as the inductive device or part thereof of the sensor module of Kovacs, since Kovacs teaches using an inductive device, and Brockway describes an appropriate such device.

Regarding claim 2, the substrate is an integral part of the sensor (see entire document, especially col. 13, lines 52-60; col. 14, lines 59-65 of Kovacs).

Regarding claims 3 and 4, the substrate is mechanically flexible and mechanically rigid (see entire document, especially col. 8, lines 21-28 of Kovacs), wherein every material has some degree of flexibility and rigidity. In the alternative, as to claim 3, see the rejection under 35 U.S.C. 103(a) set forth below.

Regarding claim 5, the electrical connections for the circuit and sensor are disposed on the substrate (see entire document, especially col. 8, lines 14-28 of Kovacs).

Regarding claim 12, the electrical circuit receives information from an external system (see entire document, especially col. 8, lines 60-65 of Kovacs).

Regarding claims 15 and 19, Kovacs, as modified further describes a miniature self contained sensor module for medical applications. The module comprises a bottom

substrate 46 defining five walls of a cavity. At least one miniature sensor 104 is disposed on the substrate. An electrical circuit 34, 36 is disposed in the bottom substrate cavity wherein the circuit receives operating power from a magnetic field with an inductor coil (see entire document, especially col. 10, lines 1-25 of Brockway), conditions a sensor signal, and transmits a conditioned sensor signal to an external signal detection system via magnetic telemetry. A top substrate encloses the sensor and electronics by forming a sixth cavity wall (see entire document, especially figs. 7, 8 of Kovacs).

Regarding claim 16, 62, and 63, the sensor includes a pressure sensor (see entire document, especially col. 13, line 41-col. 15, line 14 of Kovacs).

Regarding claim 20, the electrical connections for the circuit and sensor are disposed on a secondary substrate 40 (see entire document, especially figs. 7, 8; col. 8, lines 14-31; col. 13, lines 49-51; col. 14, lines 59-col. 15, line 5 of Kovacs).

Regarding claim 58 and 59, the module is capable of being used for any of the listed applications.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 58, 59, 62, and 63 and further in view of the applicants' arguments filed 2/23/09. Kovacs, as modified, teaches the susbtrate being made of silicon, which is disclosed by the applicants as being "rigid", but lacks the substrate being mechanically flexible. However, the applicants have further disclosed that susbtrates of rigid and flexible materials are well known and

ubiquitous in the fabrication of semiconductor devices (see p. 4 of the applicants' arguements filed 2/23/09). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a flexible material as the substrate of Kovacs, in light of applicants' admission that the species are obvious variants.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 58, 59, 62, and 63 above, and further in view of US Patent Application Publication No. 2003/0013969 to Erikson et al. Regarding claim 6, Kovacs lacks the electrical connections for the electrical circuit and sensor being disposed on a secondary substrate. However, Erikson teaches a sensor 30 and circuitry 18 disposed on a first substrate, wherein electrical connections for the circuit and sensor are disposed on a secondary substrate (see entire document, especially fig. 1; paragraphs 69-73, 91, 92 of Erikson). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the secondary substrate of Erikson with the sensor module of Kovacs, as it would merely be the substitution of one known arrangement for another.

Regarding claim 7, the electrical connections are apportioned among the first and second substrates (see entire document, especially fig. 1 of Erikson).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway and Erikson, as applied to claims 6 and 7 above, and further in view of the applicants' arguments filed 2/23/09. Kovacs, as modified, teaches the secondary

substrate being made of silicon (see entire document, especially paragraphs 42, 84 of Erikson), which is disclosed by the applicants as being "rigid", but lacks the substrate being mechanically flexible. However, the applicants have further disclosed that substrates of rigid and flexible materials are well known and ubiquitous in the fabrication of semiconductor devices (see p. 4 of the applicants' arguements filed 2/23/09). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a flexible material as the substrate of Kovacs, as modified, in light of applicants' admission that the species are obvious variants.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 58, 59, 62, and 63 above, and further in view of US Patent Application Publication No. 2003/0013969 to Erikson. Regarding claims 9-11 Kovacs, as modified, is silent as to how the circuitry and sensor are connected to the substrate. However, Erickson teaches using solder to connect circuitry and a sensor to a substrate (see entire document, especially paragraph 35 of Erikson). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use solder to connect the circuitry of Kovacs, as modified, to the substrate, since Erikson teaches solder as an appropriate such means for connecting circuitry and/or a sensor to a substrate. The combination results in the connection of the substrate to the coil being achieved through at least solder, since the coil is connected to the circuitry, and the circuitry is soldered to the substrate.

Claims 13, 14, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 20, 58, 59, 62, and 63 and further in view of US Patent No. 5,067,491 to Taylor, II et al. Kovacs, as modified, lacks the sensor module being coated with at least one layer of thin coating. However, Taylor teaches coating an implantable device with parylene to protect the device from damage by body fluids and prevent the need for an anticoagulant or coating an implantable device with parylene and heparin in order to further enhance antithrombogenicity (see entire document, especially col. 1, line 46-col. 2, line 9; col. 2, line 52-col. 3, line 7 of Taylor). Therefore, it would have been obvious to one of ordinary skill in the art to combine the coating of Taylor with the sensor module of Kovacs, as modified, in order to protect the device from damage by body fluids and prevent the need for an anticoagulant or in order to further enhance antithrombogenicity.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 20, 58, 59, 62, and 63 above, and further in view of US Patent No. 5,951,487 to Brehmier-Flick et al. Kovacs, as modified, discloses combining multiple sensors in the sensor module (see entire document, especially col. 8, lines 60-67 of Kovacs) and further describes a module comprising a temperature sensor (see entire document, especially col. 9, lines 1-17 of Kovacs) and a module comprising a pressure sensor (see entire document, especially col. 14, line 59-col. 15, line 15 of Kovacs). Kovacs fails to explicitly disclose a module

having both a pressure a temperature sensor. However, Brehmeier-Flick teaches an implantable sensor module having both a pressure and temperature sensor (see entire document, especially claim 4 of Brehmeier-Flick). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the module of Brehmeier-Flick with that of Kovacs, as modified, to provide a pressure and temperature sensor in the module of Kovacs, as modified, since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of invention.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 20, 58, 59, 62, and 63 above, and further in view of US Patent No. 5,807,258 to Cimochowski et al. Kovacs, as modified, discloses combining multiple sensors in the sensor module (see entire document, especially col. 8, lines 60-67 of Kovacs) and further describes a module comprising a pressure sensor (see entire document, especially col. 14, line 59-col. 15, line 15 of Kovacs). Kovacs fails to explicitly disclose a module having both two pressure sensors. However, Cimochowski teaches an implantable sensor module having two pressure sensors (see entire document, especially col. 5, lines 11-21 of Cimochowski). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the module of Cimochowski with that of Kovacs, as

modified, to provide two pressure sensors in the module of Kovacs, as modified, since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of invention.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway, as applied to claims 1-5, 12, 15, 16, 19, 20, 58, 59, 62, and 63 above, and further in view of the applicants' arguments filed 2/23/09. Regarding claim 21, Kovacs, as modified, teaches the secondary substrate being made of silicon (see entire document, especially col. 8, lines 21-23 of Kovacs), which is disclosed by the applicants as being "rigid", but lacks the substrate being mechanically flexible. However, the applicants have further disclosed that substrates of rigid and flexible materials are well known and ubiquitous in the fabrication of semiconductor devices (see p. 4 of the applicants' arguements filed 2/23/09). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a flexible material as the substrate of Kovacs, as modified, in light of applicants' admission that the species are obvious variants.

Regarding claim 22, the substrate connects to the sensor at a recess or cavity in the bottom substrate (see entire document, especially figs. 2-9 of Kovacs).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs in view of Brockway and the applicant's disclosure, as applied to claims 21 and 22 above. Kovacs, as modified, teaches the flexible substrate aligning with the bottom substrate recess or cavity, but lacks either substrate or the recess having a matched wedge shape. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the cavity or substrates in any reasonable shape, including a wedge shape because the applicants have not disclosed that a wedge shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, moreover, would have expected the applicants' invention to perform equally well with the cavity and/or substrates having any reasonable matching shape because the shape of the cavity and/or substrates does not affect the ability of the module to operate. Therefore, it would have been an obvious matter of design choice to modify Kovacs, as modified, to obtain the wedge shape, as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735